

Application No.: 10/769,532
Amendment and Response dated January 29, 2009
Reply to Office Action of September 29, 2008
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Remarks/Arguments:

Introduction

Claims 1-9, 11-14, 19, 21, 36, 39 and 41-56 are pending.

Objection to the Drawings

Applicants respectfully submit that with the amendment to the Specification, the objection to the drawings raised by the examiner is obviated. Reconsideration and withdrawal of the objection to the drawings is respectfully requested.

Section 112 Rejections

Claims 11-14 and 18 were rejected to under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicants respectfully submit that with the amendments to claims 11-14 and 18, the objection raised by the examiner is obviated. Reconsideration and withdrawal of the Section 112 is respectfully requested.

Section 103 Rejections

Claims 1-9, 11-14, 19, 21, 36, 39 and 41-56 were rejected under 35 U.S.C. §103(a) as allegedly being obvious over US 2002/0103527 to Kocur et al. (hereinafter "Kocur") in view of WO 99/39662 to Chobotov (hereinafter "Chobotov") and US6,051,648 to Rhee et al. (hereinafter "Rhee"). Applicants respectfully traverse.

Kocur is directed to a stent-graft where the graft has a pocket for the introduction of a therapeutic agent. Chobotov is directed to an endovascular graft having, *inter alia*, inflatable cuffs and channel(s).

As acknowledged by the examiner, Kocur fails to disclose, teach or suggest that its therapeutic agent may include an inflation medium comprising a curable liquid comprising a therapeutic agent-carrying host polymer, as set forth in the independent claims of the subject application.

The examiner asserts that Rhee teaches the use of a cross-linking host polymer for containing bioactive materials in conjunction with a graft at column 18, line 21. The examiner, however, expressly ignores the other teachings of Rhee directed to that very embodiment cited by the examiner. For example, Rhee specifically requires that its cross-linking polymer containing a bioactive substance must contact a native tissue surface. (Rhee, column 17, lines 60-61). In addition to contacting a native tissue surface, Rhee's polymer may also contact a non-native surface, such as a stent-graft. (Rhee, column 18, lines 5-21). Thus, Rhee fails to teach or suggest that its curable compositions will be useful for transporting a therapeutic agent to native tissue where its composition fails to contact such native tissue. In other words, there is not teaching, suggestion and/or expectation in Rhee that its compositions may be used within the inflatable channel of the present invention.

As Kocur fails to teach or suggest an inflation medium comprising a curable liquid comprising a therapeutic agent-carrying host polymer, as set forth in the independent claims of the subject application, may be useful with its channel, there is no motivation to alter the specific teachings of Rhee. In other words, Kocur teaches that a therapeutic agent may be used within a channel of fold of its graft. Kocur fails to teach or suggest that an inflation medium comprising a therapeutic agent and a curable liquid comprising a therapeutic agent-carrying host polymer may be useful for delivery of its therapeutic agent through the wall of its graft to the tissue of a bodily lumen.

In establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* It is only through hindsight reconstruction and selective picking and choosing does the Examiner attempt to reach the present invention through the combination of Kocur, Chobotov and Rhee. It is also well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Appellant's disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993). Such hindsight

reconstruction by the Examiner is clear as Kocur, Chobotov and Rhee fail to teach or suggest the limitations of the subject invention. Indeed, the only teaching of the use of an inflation medium comprising a therapeutic agent and a curable liquid comprising a therapeutic agent-carrying host polymer within an inflatable porous channel of a graft is the subject application.

Moreover, the Supreme Court addressed the standard for obviousness in its decision of *KSR International Co. v. Teleflex Inc., et al.*, 550 U.S. 389; 127 S.Ct. 1727; 167 L.Ed.2d 705; 82 U.S.P.Q.2d 1385 (2007). In order for an examiner to establish a *prima facie* case of obviousness after *KSR*, some degree of predictability is necessary. (82 U.S.P.Q.2d at 1395-97). *Takeda Chemical Industries Ltd. V. Alphapharm Pty. Ltd.*, 83 USPQ.2d 1169 (Federal Circuit 2007) is a post *KSR* decision in which the Federal Circuit articulated standards for establishing non-obviousness which again includes predictability of success. (83 USPQ.2d at 1176-79). Further, Section 2143.02 (II) of the MPEP states that "Obviousness does not require absolute predictability, however, at least some degree of predictability is required."

Clearly, the disclosures of Kocur, Chobotov and Rhee do not provide sufficient predictability or expectation to support a *prima facie* case of obviousness as none of these references, individually or in combination, disclose, teach or suggest the use of an inflation medium comprising a therapeutic agent and a curable liquid comprising a therapeutic agent-carrying host polymer within an inflatable porous channel of a graft. As none of these references, individually or in combination, disclose, teach or suggest the present invention, the examiner must provide some reasoning with some degree of predictability of success that one of ordinary skill in the art would modify Kocur, Chobotov and Rhee in an attempt to arrive at the present invention. In particular, the examiner offers no reasoning to modify the specific teaching of Rhee that requires its curable compositions to be in direct contact with native tissue so that its bioactive agent within its composition may be used. There is no other reference of record that teaches or suggests that the compositions of Rhee may somehow be modified so they do not have to contact native tissue and still be useful for their intended purpose.

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Clearly, the expectation and predictability to arrive at the present invention through Kocur, Chobotov and Rhee do not rise to a level that represents a *prima facie* case of obviousness. It is only through impermissible hindsight reconstruction by using the subject application as a roadmap does the examiner attempt to present a *prima facie* case of obviousness.

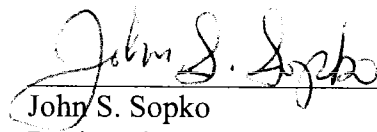
Thus, independent claims 1, 21 and 39 are patentably distinct over Kocur, Chobotov and Rhee, individually or in combination. Therefore, reconsideration and withdrawal of the rejections of independent claims 1, 21 and 39 are respectfully requested.

Summary

Therefore, Applicants respectfully submit that independent claims 1, 21 and 39, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,



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